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Michael R. Krawczsnek Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			EXAMINER KOLKER, DANIEL E	
			ART UNIT 1649	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/664,422

**Applicant(s)**

ROULEAU ET AL.

**Examiner**

DANIEL KOLKER

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 17, 20, 23, 24 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 17, 20, 23, 24 and 29-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Sequence alignment (7 pgs)

### **DETAILED ACTION**

1. The remarks and amendments filed 9 January 2008 have been entered. Claims 14, 17, 20, 23 - 24, and 29 - 35 are pending and under examination.

### ***Withdrawn Rejections***

2. The following rejections set forth in the previous office action are withdrawn:
  - A. The rejection under 35 USC 112, first paragraph, for recitation of new matter (paragraph number 6, spanning pp. 7 – 8 of the office action mailed 9 October 2007) is withdrawn in light of the amendments and arguments. The disclosure as originally filed describes what is now claimed. The examiner notes that applicant's indication that the ATG start codon begins at nucleotide 633 of SEQ ID NO:65 is particularly helpful in understanding that the disclosure provides written description of the claimed invention.
  - B. The rejection under 35 USC 102(b) over Clare is withdrawn upon further consideration and in light of the arguments presented 9 January 2008. While the Clare publication refers to the nucleic acids encoding human sodium channel 3 protein by name, the reference is not an enabling reference. According to MPEP 2121.01, with respect to a prior art reference used in a rejection under 35 USC 102,

A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

In the instant situation, Clare indicates that "three overlapping clones encoding the type III sequence were obtained from adult cerebellum and fetal total brain" (p. 80 second paragraph), and that these were later assembled into a single clone. However the reference gives no indication as to where the cDNA libraries were obtained, and gives no indication as to what probe was used to isolate the sodium-channel-encoding cDNAs. The reference fails to provide a teaching as to how to screen a library to arrive at the invention now claimed. While p. 83 first complete paragraph indicates that a probe from the 5' untranslated region was used in Northern blot experiments, there is no indication as to what sequences were used in such experiments. The examiner has determined that the Clare reference is not an enabling disclosure, as one of

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ordinary skill in the art could not have combined his or her own knowledge with the very limited description in Clare to make the claimed invention.

***Rejections and Objections Necessitated by Amendment***

***Claim Objections***

3. Claim 35 is objected to because of the following informalities: it recites “an valine” which is grammatically incorrect; it should read “a valine”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 17, 20, 23 – 24, 29 – 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 14 and 29, as well as claims depending therefrom, are indefinite because they require both the presence of an explicitly identified sequence and simultaneously require variation from that sequence. For example, claim 14 recites “A purified human nucleic acid molecule comprising... (a) the nucleic acid sequence of SEQ ID NO:65... (b) a nucleic acid sequence encoding.. SEQ ID NO:67.... wherein said nucleic acid sequence of (a), (b), or (d) comprises a mutation..”. This is confusing: does the nucleic acid claimed actually comprise SEQ ID NO:65 (as recited in (a)) or comprise a sequence encoding SEQ ID NO:67 (as recited in (b)), or alternatively does the claimed nucleic acid sequence instead have a mutation (as required by the “wherein” clause)? Both cannot be true. Similarly, claim 23 requires both the presence of SEQ ID NO:65 and variation from that sequence. Claim 29 requires the presence of a nucleic acid encoding SEQ ID NO:67 and the presence of a mutation. The remaining claims depend from a rejected base or intermediate claim but do not clarify the scope of patent protection desired.

Note that claims 34 and 35 are not subject to this rejection. Claims 34 and 35 are drawn to nucleic acids which are variants of SEQ ID NO:65, thus it is clear that SEQ ID NO:65 is not present, but rather that a variant is present.

In order to overcome this rejection, it is recommended that applicant re-write the claims to more clearly reflect which nucleic acid sequences must be present in the claimed invention.

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Additionally, if applicant is attempting to claim specific mutations, applicant may submit a new sequence listing which specifically identifies those mutated sequences. For example, rather than reciting "a G to A mutation corresponding to...." as set forth in claim 14 part (ii), applicant could submit a new sequence listing which spells out this sequence in full. Applicant is welcome to contact the examiner directly at 571-272-3181 if any questions remain on this issue. Applicant is reminded that any newly-submitted sequences (e.g. directed to mutations) must find support in the disclosure as originally filed. If a substitute sequence listing is submitted, it must comply with the sequence rules. See MPEP § 2426 for instructions on submission of replacement sequence listings.

5. Claims 14, 17, 20, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, part (f), reads "a nucleic acid encoding". It is unclear what the nucleic acid encodes. The skilled artisan could not determine which nucleic acids are within the scope of this part of the claim and which nucleic acids are outside the scope of the claim.

Claims 17, 20, and 24 depend from rejected claim 14 but do not clarify the scope of patent protection sought.

#### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34 – 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 34 and 35 are each drawn to variants of nucleic acid sequences. There is no specific recitation in the claim of which structures, if any, are to be maintained in the variant. At p. 18 lines 22 - 24, the specification defines "variants" of nucleic acids to be "substantially similar

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in structure and biological activity to the... nucleic acid of the present invention." No degree of similarity is recited either in the definition or in claims 34 – 35, thus they appear to encompass unlimited numbers of possible substitutions. While claim 34 requires that the variant encode a sodium channel, there is no description of which structures are either necessary or sufficient for the variant to be a sodium channel. There is no description or definition of when the variant ceases to encode a sodium channel. Note that claim 35 does not have the requirement that the nucleic acid encode a sodium channel, and thus seems to encompass any and all nucleic acids that happen to have "a deletion mutation which deletes a codon corresponding to asparagine at position 43 of SEQ ID NO:67" or "a G to A mutation corresponding to an valine to isoleucine at amino acid 1035 of SEQ ID NO:67."

The specification fails to provide evidence of possession of the full genus of variants of human nucleic acids as claimed. There is no identification of partial or complete structure of the variants, or of elements common to all members of these broad genera. Applicant is directed to the newly-issued Written Description Training Materials, available on the USPTO's website at <http://www.uspto.gov/web/menu/written.pdf>. See particularly Example 9, on pp. 31 - 32, which is drawn to protein variants. The fact pattern in that hypothetical example is similar to that of the instant case. Note that while the discussion in the example is on point to proteins, the same logic applies to nucleic acids as claimed.

7. Claims 34 – 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that differ from SEQ ID NO:65 by either (i) a mutation that results in deletion of the AAT triplet starting 126 nucleotides from an initiator codon at nucleotide 633 of SEQ ID NO:65 or (ii) a G to A mutation at nucleotide 3102 from an initiator codon at nucleotide 633 of SEQ ID NO:65, does not reasonably provide enablement for the full scope of variants as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of

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experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

In this case, the nature of the invention is complex. The claims are broad in that they are drawn to variants of the nucleic acid of SEQ ID NO:65. While the claims require that certain specific elements be mutated or deleted, the claims do not require any particular elements of the nucleic acid sequence of SEQ ID NO:65 to be retained. At p. 18 lines 22 - 24, the specification defines "variants" of nucleic acids to be "substantially similar in structure and biological activity to the... nucleic acid of the present invention." No degree of similarity is recited either in the definition or in claims 34 - 35, thus they appear to encompass unlimited number of possible substitutions. The skilled artisan would have to undertake a great deal of experimentation in order to make all possible nucleic acid sequences encompassed by these claims, since there is no recitation of any elements that are actually present, beyond what is implied by the two mutations. Although claim 34 requires that the nucleic acid variant encode a sodium channel, no structural elements are required to be present in the nucleic acid or encoded protein. Claim 35 does not even require that the claimed variant nucleic acid encode a sodium channel, so it reads on nucleic acids which encode non-functional proteins that the specification has not shown how to use. Alberts et al. (Molecular Biology of the Cell, 3<sup>rd</sup> Edition, 1994, pp. 98 - 104) teaches that changes in nucleic acids will result in changes in protein shape, which would be expected to change the biochemical properties of the protein. Since claim 35 allows for the encoded protein to either be non-functional or something other than a sodium channel, and the specification only teaches the skilled artisan how to use sodium channels, the artisan would have to discover, on his or her own, the function of the full scope of nucleic acids of claim 35, as well as the proteins encoded by them. Given the lack of adequate guidance in the specification, the large degree of experimentation required would clearly be undue.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 14, 23 – 24, and 34 – 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu (February 1998. *Journal of Molecular Neuroscience* 10:67-70, cited as reference C74 on IDS filed 16 May 2005), as evidenced by sequence alignment and by GenBank AF035685 and AAC29514.1 entries.

Lu teaches isolation of nucleic acids encoding human sodium channels. Specifically, the reference teaches isolation of two sequences, which have been deposited with GenBank accession numbers AF035685 and AF035686 respectively. See abstract, which indicates that the sequences were deposited with GenBank. The AF035685 sequence contains many stretches of 100% identity with applicant's SEQ ID NO:65. Note nucleotides 580 - 986 from applicant's SEQ ID NO:65 are 100% identical to nucleotides 2 - 417 from AF035685; nucleotides 999 – 1234 from applicant's SEQ ID NO:65 are 100% identical to nucleotides 421 - 666 from AF035685; nucleotides 2500 – 4725 from applicant's SEQ ID NO:65 are 100% identical to nucleotides 1922 - 4147 from AF035685; see attached sequence alignment. Given the very large regions of 100% identity between the two sequences, the prior art sequence (AF035685) will hybridize to the full-length sequence of SEQ ID NO:65 under the conditions recited in claim 14 part (d). The sequence from Lu (AF035685) encodes a sodium channel. Thus the prior art sequence has every structural element recited in claim 14 part (d). As set forth above in the rejection under 35 USC 112, second paragraph, claim 14 is confusing because it is unclear whether the mutations recited in parts (i) and (ii) must be present. However, it is noted that the GenBank entry for AF035685 indicates that the encoded protein has the accession number AAC29514.1; careful inspection of the protein sequence listed there indicates that there is not an asparagine at residue 43, so the residue has been deleted. The prior art nucleic acid anticipates claim 14.

Claim 23 is anticipated as the codon for asparagine at residue 43 is not present. Claim 24 is anticipated as it requires no structural elements beyond those recited in claim 14. Since the prior art has every structural feature recited in claim 14, it must have the recited property; see MPEP § 2112.01(I) and (II). Claims 34 and 35 are anticipated as they require no specific structural features other than the nucleic acid encode a sodium channel (claim 34) and that no asparagine be present at amino acid 43 of the encoded protein. As set forth in the preceding paragraph, the prior art sequence has both these features, so it anticipates these claims.



***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 17, 20, 23 – 24, 30 – 31, and 34 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lu (February 1998. Journal of Molecular Neuroscience 10:67-70) in view of Delgado (U.S. Patent 6,030,810).

The reasons why claims 14, 23 – 24, and 34 – 35 are anticipated by Lu are set forth in the rejection under 35 USC 102(b) above. Briefly, Lu teaches nucleic acids encoding sodium channels; given the large stretches of identity between Lu's sequence and applicant's SEQ ID NO:65, the nucleic acid molecules will hybridize. However while Lu teaches the nucleic acid sequences, the reference does not explicitly teach vectors comprising the nucleic acids as recited in claims 17 and 30, or cells comprising the vectors, as recited in claims 20 and 31.

Delgado teaches nucleic acids encoding sodium channels. See for example column 4 lines 45 – 61; see also claim 1. Delgado teaches that a convenient way to make the encoded protein is by placing the nucleic acid in vectors, which are then transformed into cells, which make the encoded protein. See for example column 7 line 27 - column 8 line 9, column 3 lines 12 - 25, column 13 lines 8 - 19, and claims 6 - 9. Thus the reference is on point to instant claims 17, 20, and 30 – 31. However Delgado does not explicitly teach nucleic acids which will necessarily hybridize to SEQ ID NO:65 under the conditions recited in claim 14.

It would have been obvious to one of ordinary skill in the art to use the nucleic acids of Lu to make vectors and host cells, as taught by Delgado, thereby arriving at the invention of

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claims 17, 20, and 30 – 31. The motivation to do so would be to make the encoded protein, which Delgado teaches is useful in screening assays to find novel therapeutics.

***Maintained Rejections***

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 17, 20, and 24 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO:65, nucleic acids encoding SEQ ID NO:67, and the nucleic acids that differ from either of those by the specific mutations recited in claim 14 parts (i) and (ii), does not reasonably provide enablement for the full scope of nucleic acids "wherein the presence of said nucleic acid in a sample of a subject indicated that the subject has an increased risk of idiopathic generalized epilepsy" as recited in claim 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for the reasons previously made of record. Applicant is directed to the paragraph bridging pp. 4 - 5 of the office action mailed 9 October 2007 for a more detailed explanation. Briefly, claim 24 is limited to those particular embodiments "wherein the presence of said nucleic acid in a sample of a subject indicates that the subject has an increased risk of epilepsy." The claim depends from claim 14 and encompasses nucleic acids which hybridize to disclosed sequences (see part (d)), which indicates that substantial variation can occur anywhere in the sequence. Because claim 14 part (d) does not require any particular structural elements to be present, the claim is quite broad. Similarly, claim 24 encompasses any possible variation and does not require the presence of any specific sequences to be present.

The specification fails to disclose to the skilled artisan the full scope of the nucleic acids which are indicative of an increased risk of epilepsy. While a few mutations in SCN3A-encoding nucleic acid are reported at pp. 53 – 54 of the specification, such disclosure is not commensurate in scope the breadth of claim 24. Claim 24 does not require any particular

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region of the nucleic acid be conserved or present. There is no requirement for mutation at any particular nucleotide. Thus the skilled artisan would have to determine which nucleotide positions within SEQ ID NO:65 are indicative of the subject having an increased risk of epilepsy. The art of record (Wallace, US 7,078,515) teaches that mutations to sodium-channel-encoding nucleic acids often do not result in changes to risk of having epilepsy.

The specification fails to provide guidance or working examples commensurate with the full scope of the claims. Thus the skilled artisan would have to determine, on his or her own, which nucleic acids within the long sequences encompassed by the claims indicate "that the subject has an increased risk of idiopathic generalized epilepsy" as recited in claim 24. Because of the complex nature of the invention and the lack of adequate guidance set forth in the specification, the large degree of experimentation required would be undue.

Applicant did not traverse the examiner's determination that it would require undue experimentation to make and use the full scope of nucleic acids encompassed by claims 14 and 24. Applicant indicated that certain claims have been amended to address other concerns the examiner raised in the previous office action but did not address the issue of whether undue experimentation is required to make any and all nucleic acids which indicate "that the subject has an increased risk of idiopathic generalized epilepsy" as recited in claim 24. The rejection of claims 14 and 24 stands. Claims 17 and 20 are included in this rejection as they depend from claim 14 but are not limited to subject matter that could be enabled in the absence of undue experimentation.

11. Claims 14, 17, 20, and 24 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection stands for the reasons previously made of record, particularly with respect to claim 24, and explained in further detail herein. As a preliminary matter, the examiner now considers claim 14, part (d), to be fully described. Upon further consideration of the claim, the arguments presented in the response filed 9 January 2008, and the newly-published Written Description Training Materials, available on the internet at <http://www.uspto.gov/web/menu/written.pdf> (see particularly pp. 21 – 23), the examiner

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concedes that claim 14 part (d) is described, although it is broad. Note however that claim 14 stands rejected as it encompasses claim 24, which has not been fully described.

The specification fails to describe those structures which are necessary or sufficient for the claimed nucleic acids to be an indication "that the subject has an increased risk of idiopathic generalized epilepsy" as recited in claim 24. While a very small number of mutations are described in the specification, there is not a written description of the full genus of nucleic acids which lead to increases in risk. The art of record (Wallace, U.S. Patent 7,078,515) teaches that mutations within sodium channel-encoding nucleic acids sometimes do lead to changes in epilepsy predisposition, and other times do not lead to such a change. The reasoning behind this argument was set forth on p. 6, third paragraph, of the office action mailed 9 October 2007. Applicant did not traverse the examiner's conclusion that the specification fails to describe the claimed genera, but stated that the amendments to the claims are sufficient to overcome the rejections of record. Since the specification fails to disclose to the public the structures common to all members of the genus of nucleic acids that provide the characteristic "that the subject has an increased risk of idiopathic generalized epilepsy" as recited in claim 24, the skilled artisan cannot envision those structures. The specification fails to describe the invention of claim 24 in full. Since claim 14 encompasses claim 24, claim 14 is rejected as well. Claims 17 and 20 depend from claim 14 but are not limited to subject matter fully described.

### ***Conclusion***

12. No claim is allowed.
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

April 28, 2008